

PSJ15 Exh 80

[HOME](#)[USDOJ.GOV](#)[PRIVACY POLICY](#)[CONTACT US](#)[SITE MAP](#)[Search dea.gov](#)**News Release** [print friendly page]

FOR IMMEDIATE RELEASE

Date: June 15, 2010

Contact: Rich Isaacson

Number: (313) 234-4310

Press Room[News Releases](#)[E-mail updates](#)[Speeches & Testimony](#)[Multi-Media Library](#)**About Us**[Mission](#)[Leadership](#)[History](#)[Organizational Chart](#)[Programs & Operations](#)[Wall of Honor](#)[DEA Museum](#)[Office Locations](#)**Careers at DEA****DEA Drug Information**[Drug Information Resources](#)**Law Enforcement**[Most Wanted](#)[Major Operations](#)[Threat Assessment](#)[Training Programs](#)[Stats & Facts](#)[Additional Resources](#)**Drug Prevention**[For Young Adults](#)[For Parents](#)[Additional Drug Resources](#)**Diversion Control & Prescription Drugs**[Registration](#)[Cases Against Doctors](#)**Drug Policy**[Controlled Substances Act](#)[Federal Trafficking Penalties](#)[Drug Scheduling](#)**Legislative Resources****Publications****Acquisitions & Contracts****Michigan Pharmaceutical Supplier's Dea License Suspended***-Harvard Drug Group, LLC distributed 13 million doses of Oxy from 2008-2010*

JUN 15 -- (Detroit, MI) – Robert L. Corso, Special Agent in Charge of the Detroit Field Division, Drug Enforcement Administration (DEA) announced today the Immediate Suspension of the Federal Controlled Substance Registration of Harvard Drug Group, LLC.

Harvard Drug Group, LLC, based in Livonia, Michigan, has been the subject of a DEA investigation that alleges the company was selling large quantities of controlled substances to pharmacies, primarily in Florida. The investigation has revealed that several of Harvard's largest purchasers of oxycodone were engaged in schemes to dispense controlled substances based on prescriptions that were written for other than legitimate medical purposes. The Investigation revealed that Harvard Drug Group, LLC, distributed over 13 million dosage units of oxycodone products to customers in the two year time frame between March 2008 and March 2010.

Robert L. Corso, stated, "Pharmaceutical companies have a responsibility to ensure that the drugs they sell don't end up in the hands of drug traffickers or businesses that are conducting their business illegally. Harvard Drug Group, LLC, should have known, based on the large, frequent quantities, that their customers were diverting oxycodone into arenas that were not legitimate. Today's action sends the message that the DEA is working hard to hold accountable those companies that are operating in a manner outside of federal law."

DEA's action suspends Harvard Drug Group, LLC's DEA Certificate of Registration in accordance with an Immediate Suspension Order and pursuant to Sections 303 and 304 of the Controlled Substances Act, Title 21, Sections 823 and 824. The DEA's investigation of Harvard Drug Group, LLC, has determined that the continued registration of this company constitutes an imminent danger to public health and safety.

Harvard Drug Group, LLC, received written notice of the factual and legal basis for this action. In addition, Harvard Drug Group, LLC will be given an opportunity for an administrative hearing within the next 60 days. After the hearing, the DEA Deputy Administrator will make a final decision on whether Harvard Drug Group, LLC registration should be permanently revoked. This decision will be published in the Federal Register.

Oxycodone is the generic name of an addictive prescription painkiller that is classified under federal narcotics laws as a Schedule II controlled substance. Oxycodone is typically legally prescribed to combat acute, severe pain for legitimate medical purposes. Accordingly, these prescriptions are usually for a modest number of pills to be taken over a short period of time.

This is an ongoing investigation. Please forward any questions to DEA Detroit Public Information Officer Rich Isaacson at (313) 234-4310.

Mallinckrodt-
Secker-
2/19/18

Ex. 033



THE UNITED STATES ATTORNEY'S OFFICE
DISTRICT *of* MARYLAND

[U.S. Attorneys](#) » [District of Maryland](#) » [News](#)

Department of Justice

U.S. Attorney's Office

District of Maryland

FOR IMMEDIATE RELEASE

Wednesday, June 25, 2014

Pennsylvania Pharmaceutical Wholesaler Value Drug, Inc. To Pay \$4,000,000 In Settlement

*Settles Claims that Value Drug Failed to Report Suspicious Orders of Oxycodone
to Pharmacies in Maryland and Pennsylvania*

Baltimore, Maryland – Value Drug, Inc. (Value Drug) has agreed to pay \$4,000,000 to the United States to resolve allegations that it violated the Controlled Substances Act (CSA) by failing to report suspicious orders of oxycodone to six pharmacies located in Maryland and Pennsylvania. Value Drug is a wholesale purchasing and distribution cooperative located in Altoona, Pennsylvania, that distributes pharmaceuticals, including controlled substances, to approximately 600 independent pharmacies located in Maryland, Pennsylvania and Ohio.

The settlement agreement was announced today by United States Attorney for the District of Maryland Rod J. Rosenstein and Special Agent in Charge Karl C. Colder of the Drug Enforcement Administration - Washington Field Division.

"Pharmacy wholesalers and retailers that fill unusually large or frequent orders for controlled substances without notifying the DEA violate the law and are subject to penalties," said U.S. Attorney for the District of Maryland Rod J. Rosenstein. "Abuse of pharmaceutical drugs is one of the top federal law enforcement priorities."

"DEA is responsible for ensuring that all controlled substance transactions take place within DEA regulatory closed system. All legitimate handlers of controlled substances must maintain strict accounting for all distributions and Value Drug failed to adhere to this policy," stated Special Agent-in-Charge Karl C. Colder of the Drug Enforcement Administration's Washington Division. "Oxycodone is a very addictive drug and failure to report suspicious orders of oxycodone is a serious matter. The civil penalty levied against Value Drug should send a strong message that all

handlers of controlled substances must perform due diligence to ensure the public safety," stated Colder.

The CSA requires distributors of pharmaceuticals, such as Value Drug, to identify and report suspicious orders of controlled substances, such as orders of unusual size, unusual frequency or those that substantially deviate from a normal pattern. The settlement resolves allegations that from January 1, 2009 through September 12, 2012, Value Drug failed to report suspicious orders of oxycodone to six pharmacy customers, including: Russo's Pharmacy in Hagerstown, Maryland; Zonetak Pharmacy in Owings Mills, Maryland; Philly Pharmacy- Chestnut Avenue and Philly Pharmacy- Roosevelt Boulevard both located in Philadelphia, Pennsylvania; and East Hills Pharmacy and Johnstown Pharmacy, both in Johnstown, Pennsylvania.

As part of the settlement, Value Drug will also enter into a Memorandum of Agreement (MOA) with the DEA. The MOA will resolve administrative claims that the DEA has against Value Drug and will require that Value Drug implement more effective systems and measures to detect and report suspicious orders of controlled substances. The MOA will remain in place for a period of three years.

U.S. Attorney Rod J. Rosenstein commended the DEA's Office of Diversion Control for its work in the investigation. Mr. Rosenstein thanked Assistant United States Attorney Thomas F. Corcoran, who handled the case.

Component(s):

USAO - Maryland

Updated January 26, 2015

AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO



FEDERAL REGISTER

Vol. 80

Tuesday,

No. 178

September 15, 2015

Part II

Department of Justice

Drug Enforcement Administration
Masters Pharmaceuticals, Inc.; Decision and Order; Notice

Mallinckrodt-
Becker-
2/19/18

Ex. 034

DEPARTMENT OF JUSTICE
Drug Enforcement Administration

[Docket No. 13-39]

Masters Pharmaceuticals, Inc.: Decision and Order

On August 9, 2013, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Masters Pharmaceuticals, Inc. (hereinafter, Respondent). ALJ Ex. 1. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration Number RD0277409, pursuant to which it is authorized to distribute controlled substances in schedules II through V, at the registered location of 11930 Kemper Springs, Cincinnati, Ohio, and the denial of any pending application to renew or modify its registration, on the ground that its "continued registration is inconsistent with the public interest." *Id.* (citing 21 U.S.C. 824(a)(4)).

The Show Cause Order specifically alleged that on April 21, 2009, Respondent entered into a Memorandum of Agreement (MOA) with DEA, pursuant to which it agreed "to maintain a compliance program to detect and prevent [the] diversion of controlled substances as required under the [Controlled Substances Act] and applicable DEA regulations." *Id.* (quoting MOA at ¶ II.1.a). The Order also alleged that in the MOA, Respondent "acknowledg[ed] and agree[d] that the obligations undertaken . . . do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances." *Id.*

The Order then alleged that notwithstanding "the MOA, the specific guidance provided to [Respondent] by DEA, and the public information readily available regarding the oxycodone epidemic in Florida, and in the United States, [Respondent] failed to maintain effective controls against the diversion of controlled substances . . . in violation of 21 U.S.C. 823(b)(1) and (e)(1)." *Id.* at 1–2. The Order then alleged that from April 1, 2009 through December 31, 2009, Respondent distributed more than 37 million dosage units of oxycodone nationally and that nearly 25 million dosage units "were distributed to its Florida customers," and that the latter distributions "well exceeded" its distributions to customers

in other States.³ *Id.* at 2. The Order further alleged that during 2010, Respondent distributed 37.86 million dosage units of oxycodone nationally, of which nearly 24.4 million dosage units "were distributed to its Florida customers."⁴ *Id.* Finally, the Order alleged that between January 1 and March 31, 2011, Respondent distributed 6.1 million dosage units of oxycodone nationally, of which approximately 2.76 million dosage units "were distributed to its Florida customers."⁵ *Id.*

Next, the Show Cause Order alleged that "[s]ince at least 2009, the majority of [Respondent's] largest purchasers of oxycodone . . . have been retail pharmacies in the State of Florida who [it] knew or should have known were distributing controlled substances based on . . . prescriptions that were issued for other than a legitimate medical purpose and outside [of] the usual course of professional practice." *Id.* at 3. The Order then made allegations regarding Respondent's distributions of oxycodone 30 mg to eight pharmacies. More specifically, the Order alleged that:

1. "From April 1, 2009 through November 30, 2010, [it] distributed approximately 591,800 dosage units . . . to Tru-Valu Drugs";

2. "From April 1, 2009 through January 31, 2011, [it] distributed approximately 993,100 dosage units . . . to The Drug Shoppe";

3. "From April 1, 2009 through March 31, 2011, [it] distributed approximately 333,000 dosage units . . . to the Medical Plaza Pharmacy";

4. "From April 1, 2009 through September 30, 2010, [it] distributed approximately 1,275 million dosage units . . . to Englewood Specialty Pharmacy";

5. "From April 1, 2009 through December 31, 2010, [it] distributed approximately 570,700 dosage units . . . to City View Pharmacy";

6. "From January 1, 2009 through November 30, 2010, [it] distributed approximately 1.7 million dosage units . . . to Lam's Pharmacy";

7. "From April 1, 2009 through August 31, 2009, [it] distributed approximately 637,400 dosage units . . . to Morrison's RX"; and

By contrast, the Order alleged that during this period, Respondent distributed approximately 1.47 million dosage units of oxycodone to its Nevada customers, 1.27 million to its Tennessee customers, 1.14 million to its Pennsylvania customers, and 1.09 million to its New Jersey customers. ALJ Ex. 1, at 2.

³ By contrast, the Order alleged that during 2010, Respondent distributed approximately 2.8 million dosage units of oxycodone to its Nevada customers, 2.14 million to its Tennessee customers, 1.7 million to its New Jersey customers, and 1.37 million to its Pennsylvania customers. ALJ Ex. 1, at 2.

⁴ By contrast, the Order alleged that during this period, Respondent distributed approximately 600,000 dosage units of oxycodone to its Tennessee customers, 415,000 to its New Jersey customers, 304,000 to its Pennsylvania customers, and 192,000 to its Nevada customers. ALJ Ex. 1, at 2.

⁵ From January 1, 2009 through December 2009, [it] distributed approximately 351,600 dosage units . . . to Temple Terrace Pharmacy.⁶

Id.

The Show Cause Order then alleged that Respondent "consistently ignored and/or failed to implement its own due diligence and suspicious order monitoring policies, compromising the effectiveness of those policies." *Id.* Continuing, the Order alleged that "notwithstanding the large quantities of controlled substances ordered by [its] retail pharmacy customers, [Respondent] failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted" and "Ignor[ed] and/or failed to document red flags of diversion present at many of its retail pharmacy customers." *Id.* Finally, the Order alleged that Respondent "failed to detect and report suspicious orders of oxycodone products by its pharmacy customers, as required by 21 CFR 1301.74(b)." *Id.*

Following service of the Show Cause Order, Respondent requested a hearing on the allegations. ALJ Ex. 3. The matter was placed on the docket of the Office of Administrative Law Judges, and assigned to ALJ Gail Randall (hereinafter, ALJ), ALJ's Recommended Decision (R.D.), at 1. Following pre-hearing procedures, see generally ALJ Exs. 5–11, the ALJ conducted an evidentiary hearing on February 24 through 28 and March 3 through 4, 2014, in Arlington, Virginia. Following the hearing, both parties filed briefs containing their proposed findings of fact and conclusions of law.

On June 19, 2014, the ALJ issued her Recommended Decision. Applying the public interest standard of 21 U.S.C. 823(b), the ALJ noted that the relevant factors were factors one—the maintenance of effective controls against diversion—and four—Respondent's experience in the distribution of controlled substances.

The ALJ rejected the Government's contention that Respondent had failed to report numerous suspicious orders, which it filled and shipped, upon subsequently determining that the customer was likely engaged in diverting controlled substances. R.D. at 154–61. Noting that the relevant regulation requires the reporting of a suspicious order "when discovered," 21 CFR 1301.74(b), the ALJ opined that neither the regulation's language nor its purpose "supports the conclusion that a registrant is required to review past orders from pharmacies the registrant later learns may be diverting controlled

substances.” *Id.* at 157. The ALJ did, however, conclude that the regulation “impose[s] a duty to report past orders [that] the registrant *actually* discovers were suspicious.” *Id.* at 158. However, based on her review of the record, the ALJ concluded that Respondent had only failed to report a single suspicious order. *Id.*

Turning to the Government’s contention that Respondent had failed to maintain effective controls against diversion, the ALJ concluded that the Government’s evidence as to the volume of Respondent’s sales to Florida and the eight pharmacies in particular did not support a finding that it was in violation of this duty. *Id.* at 164–67. As the ALJ explained, “the sheer volume of a respondent’s controlled substances sales or purchases, without some kind of contextual background to link the sales to the respondent’s duty under the CSA, cannot be used to indicate that the distributor’s registration would be against the public interest.” *Id.* at 164. The ALJ further noted that the Government did not present a “statistical expert or any other evidence to explain why the volume of Respondent’s sales was necessarily indicative of diversion.” *Id.* at 166. She also credited the testimony of Respondent’s statistical expert that the “shipments to the DEA-identified pharmacies rarely stand out from the rest of the monthly shipments”; that because Respondent does not have access to the Agency’s ARCOS database, “it cannot compare its shipments to [those] made by other distributors”; that “Respondent’s business model as a secondary supplier made comparisons across pharmacies practically useless”; and that comparing its distributions to Florida customers with those in other States was not “very meaningful because there [are] so many factors that are relevant.” *Id.* at 167 (citations omitted).

Next, the ALJ rejected the Government’s contention that Respondent failed to follow its own policies and procedures. *Id.* at 170–79. The ALJ first found that Respondent’s Policies and Procedures required that an order placed on compliance hold by its Suspicious Order Monitoring System (SOMS) be subject to additional due diligence which included: (1) Contacting the customer to discern the reason for the deviation in size, pattern, or frequency; (2) independently verifying the reason stated by the customer; and (3) conducting a complete file review. *Id.* at 73–74, 76–77. While the Government cited numerous instances in which Respondent’s employees released orders

without documenting having performed the above steps, the ALJ rejected its contention, reasoning that Respondent’s Policies and Procedures did “not require documentation of the reasons for the release of a held order.” *Id.* at 171. And while noting “that Respondent documented some reasons for abnormal orders,” she further reasoned that “[t]he mere absence of documentation—documentation that is not required by Respondent’s Policies and Procedures, DEA regulations, or any established industry standard—does not constitute substantial evidence that the undocumented act did not occur.” *Id.* at 172; *see also id.* at 173–74, 176.

Next, the ALJ addressed the Government’s contention that Respondent failed to properly use the Utilization Reports (URs) which it obtained from its pharmacy customers. *Id.* at 179–95. While the ALJ found that Respondent was required under its policies and procedures to obtain a UR from a pharmacy customer whenever it placed an order on compliance hold and yet repeatedly failed to do so, *id.* at 181, she otherwise rejected the Government’s contention that Respondent did not properly utilize the URs in its review of the held orders. *Id.* at 181–92.

In rejecting the Government’s contention, the ALJ explained that because DEA was obligated under a Memorandum of Agreement (MOA) to conduct a compliance review and notify Respondent of any deficiencies in its policies and procedures and failed to do so with respect to its use of the URs, the MOA bars the Agency “from sanctioning Respondent for not implementing additional UR analyses into its Policies and Procedures.” R.D. at 186. While noting the parties’ agreement “that controlled substance ratios are an important aspect that should be investigated prior to shipping controlled substances,” the ALJ then reasoned that “[t]he Government offered no evidence that accurate information regarding controlled substance ratios can *only* be acquired through URs.” *Id.* at 188–89. She also rejected the Government’s contention that Respondent’s actions in editing or deleting orders that were placed on hold by the SOMS established that it did not maintain effective controls against diversion or failed to report suspicious orders, noting that Respondent edited and deleted orders “for business reasons.” *Id.* at 196.

While acknowledging that the Government had proved that Respondent had failed to report a single suspicious order, the ALJ reasoned that “Respondent fills many orders each year and has reported hundreds of suspicious orders, so one minor

oversight does not render the entire system ineffective.” *Id.* at 201. The ALJ thus concluded that Respondent had “substantially complied with 21 CFR 1301.74(b),” and that its failure to report the suspicious order did not justify the revocation of its registration. *Id.*

As for her finding that Respondent had violated its own policies and procedures by failing to obtain a UR every time an order was held by the SOMS, the ALJ reasoned that “the relevant question . . . is not simply whether Respondent failed to follow its policies, but whether such failure rendered [its] system [for maintaining effective controls] ineffective . . . and/or constituted negative experience distributing controlled substances so as to justify revocation.” *Id.* The ALJ then explained that Respondent’s failure to follow its policies and procedures did not render them ineffective *per se* and that the Government was required to show that diversion was the “direct and foreseeable consequence” of its failure to follow its policy in order to establish that its due diligence program was ineffective. *Id.* at 202. Because “the Government made no showing that the shipments Respondent made without requiring URs were likely to be diverted,” or “that updated URs, had they been requested, would have indicated that the drugs were likely to be diverted,” the ALJ concluded that Respondent’s failure to obtain the URs did not “justify revocation.” *Id.* The ALJ thus recommended that Respondent be allowed to retain its registration and that the Administrator approve any pending renewal application. *Id.* at 203.

Both parties filed Exceptions to the ALJ’s Recommended Decision. Thereafter, the record was forwarded to me for final agency action. Having reviewed the record in its entirety, and having carefully considered the ALJ’s Recommended Decision as well as the parties’ Exceptions,* I respectfully reject the ALJ’s decision for reasons explained throughout this decision.

To summarize my reasons, I do agree with the ALJ that the Government’s evidence as to the volume of Respondent’s sales to the Florida pharmacies and the State in general does not constitute substantial evidence that the pharmacies were likely diverting controlled substances. I also agree with the ALJ’s rejection of the Government’s contention that Respondent, upon terminating a customer because it was likely diverting controlled substances, was obligated to review the customer’s past orders and

* I address the various exceptions raised by the Parties throughout this decision.



THE UNITED STATES ATTORNEY'S OFFICE
SOUTHERN DISTRICT *of* NEW YORK

[U.S. Attorneys](#) » [Southern District of New York](#) » [News](#) » [Press Releases](#)

Department of Justice

U.S. Attorney's Office

Southern District of New York

FOR IMMEDIATE RELEASE

Friday, December 23, 2016

Manhattan U.S. Attorney Announces \$10 Million Civil Penalty Recovery Against New York Pharmaceutical Distributor Kinray, LLC.

The Recovery Is Part of a \$44 Million Nationwide Civil Penalty Settlement with Kinray, LLC., and Its Parent Company, Cardinal Health, Inc.

Preet Bharara, the United States Attorney for the Southern District of New York, and James Hunt, Special Agent in Charge for the Drug Enforcement Administration ("DEA"), announced the filing and settlement of a civil lawsuit involving Controlled Substances Act ("CSA") claims brought by the United States against Kinray, LLC. ("Kinray"), a New York-based pharmaceutical subsidiary of Cardinal Health, Inc. ("Cardinal"). The suit was filed on December 19, 2016. In the consent decree approved yesterday by U.S. District Judge Ronnie Abrams, Kinray agreed to pay \$10 million to the United States, and admitted and accepted responsibility for failing to inform the DEA, as required by CSA regulations, of Kinray's receipt of suspicious orders for certain controlled substances during the time period between January 1, 2011 and May 14, 2012.

Under CSA regulations, pharmaceutical distributors (like Kinray) have a responsibility to report suspicious orders of unusual size, orders that deviate substantially from a normal pattern, or orders of unusual frequency. The DEA relies on this requirement, and on pharmaceutical distributors in particular, as the first line of defense against dishonest medical professionals who fuel the illegal market for opioids.

Pharmaceutical companies, as the makers and distributors of dangerous opioids, have a particular obligation not to fulfill shipments to medical professionals, pharmacies, or other entities that place unusual orders, oversized orders, or orders of unusual frequency. As alleged in the Complaint filed by this Office, and as admitted in the settlement agreement (the "Consent Decree"), Kinray violated this requirement.

Manhattan U.S. Attorney Preet Bharara said: "With the opioid crisis reaching epidemic proportions, pharmaceutical companies must be part of the solution, not part of the problem. When distributors like Kinray fail to alert the DEA to suspicious order activity, they end up facilitating the illegal sale and distribution of highly addictive opioids. Today's settlement is part of our ongoing efforts to use all the tools at our disposal to combat opioid abuse."

DEA Acting Special Agent in Charge James Hunt said: "While over 33,000 opioid-related deaths last year have drawn the attention of families and friends wanting to know more about opioid addiction; law enforcement has been red flagging pharmaceutical diversion. DEA Diversion Investigators conduct

237

Ex.
Walter R. Scott
Decker
12/17/18

12/17/2018

Manhattan U.S. Attorney Announces \$10 Million Civil Penalty Recovery Against New York Pharmaceutical Distributor Kinray, Llc. | USA...

regulatory visits in order to confirm companies adhere to strict security measures and reporting responsibilities in a timely matter to deter prescription medication from being illegally distributed. This settlement is a clear message that law enforcement is looking at pharmaceutical suppliers responsible for safeguarding and distributing prescription medication as well as targeting those responsible for its diversion."

According to the allegations in the Complaint and the terms of the Consent Decree:

Kinray, a subsidiary of Cardinal, is a pharmaceutical distributor located in Whitestone, Queens, New York. Among other things, Kinray distributes controlled substances, including Schedule II narcotics (such as oxycodone and its derivatives), to pharmacies, doctors, and medical facilities with a legitimate medical need.

Under regulations promulgated by the DEA, distributors of controlled substances must design and operate a system to disclose suspicious orders of controlled substances, and report any discovered suspicious orders to the DEA. These reporting requirements are an integral part of the DEA's efforts to track the illicit distribution of oxycodone and other highly addictive opioids.

As alleged, during the period from January 1, 2011 to May 14, 2012, the DEA investigated pharmacies in New York City and elsewhere that had placed orders for shipments of oxycodone or hydrocodone (both Schedule II controlled substances) from Kinray that were of unusual size and/or unusual frequency. For example, the DEA's internal tracking system revealed that during the relevant period, Kinray had shipped oxycodone or hydrocodone to more than 20 New York-area pharmacy locations that placed orders for a quantity of controlled substances many times greater than Kinray's average sales of controlled substances to all of its customers. Such orders should have triggered "red flags" in Kinray's ordering system, and Kinray should have reported the suspicious orders to the DEA. But for most of this time period, Kinray did not report a single suspicious order to the DEA.

In the Consent Decree entered yesterday by Judge Abrams, Kinray admitted that during the period January 1, 2011 to May 14, 2012, it failed to inform the DEA, as required, that certain orders for controlled substances it received from customers were suspicious. Kinray also agreed to pay the United States a \$10 million civil penalty, and agreed to voluntarily submit to DEA inspections of its Whitestone, New York, facility at any time without condition and without advance notice.

In addition, in a separate administrative action, on December 16, 2016, Kinray signed a Memorandum of Agreement with the DEA in which Kinray agreed to revise its standard operating procedures to improve the processes that govern its handling and delivery of controlled substances to its customers.

This settlement is part of a \$44 million global resolution announced today by the Department of Justice with Kinray's parent company, Cardinal, in which Cardinal agreed to pay an additional \$34 million to the United States to resolve failure to report suspicious order claims brought by the U.S. Attorney's Offices for the Middle District of Florida, the District of Maryland, and the Western District of Washington.

Mr. Bharara praised the outstanding investigative work of the DEA and thanked the New York City Police Department for its assistance.

The case is being handled by the Office's Civil Frauds Unit. Assistant United States Attorney Louis A. Pellegrino is in charge of the case.

Attachment(s):

[Download Kinray Consent Decree](#)

Component(s):

[USAO - New York, Southern](#)

12/17/2018 Manhattan U.S. Attorney Announces \$10 Million Civil Penalty Recovery Against New York Pharmaceutical Distributor Kinray, Llc. | USA...

Press Release Number:

16-351

Updated December 23, 2016

Message

From: Chrissy madden [cmadden@mastersrx.com]
Sent: 6/10/2011 3:47:37 PM
To: Becker, Steven A [/O=THCG/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=STEVEN.BECKER]
Subject: fyi
Attachments: image001.gif; image002.jpg

Local Drug Supplier's Controlled Drug License Suspended

POSTED: 8:57 am EDT June 10, 2011
 UPDATED: 9:24 am EDT June 10, 2011

 SHARE 

CINCINNATI -- A local drug distributor is being accused of supplying controlled substances to purchasers who intended to sell them illegally.

The Drug Enforcement Administration announced Friday the immediate suspension of the Federal Controlled Substance Registration of KeySource Medical, a wholesale supplier of pharmaceuticals in Cincinnati.

The agency said KeySource Medical has been the subject of a DEA investigation that alleges the company was selling large quantities of controlled substances to pharmacies, primarily in Florida.

The DEA said the investigation revealed that several of KeySource Medical's largest purchasers of oxycodone were engaged in schemes to dispense controlled substances based on prescriptions that were written for other than legitimate medical purposes. The investigation revealed that KeyStone Medical distributed approximately 48 million dosage units of oxycodone products to customers in Florida between November 2008 and November 2010.

"Pharmaceutical companies have a responsibility to ensure that the drugs they sell don't end up in the hands of drug traffickers or businesses that are conducting their business illegally. Prescription drug abuse in Florida, southern Ohio and northern Kentucky has risen to epidemic proportions, and KeySource Medical should have known based on the large, frequent quantities, that their customers were diverting oxycodone into arenas that were not legitimate," Special Agent-In-Charge Robert L. Corso said in a news release. "This action is another reminder that the DEA is working hard to hold accountable those companies who choose to operate outside the law."

The DEA's investigation of KeySource Medical has determined that the continued registration of this company constitutes an imminent danger to public health and safety.

Oxycodone is typically legally prescribed to combat acute, severe pain, but is also one of the most abused prescription drugs.

KeySource Medical's website indicates the company is celebrating its 15th year in business.

Read more: <http://www.wlwt.com/money/28194674/detail.html#ixzz1Ot9Dgxxz>

Chrissy Madden
 Masters Pharmaceutical
 Senior Purchasing Manager
 Phone (800) 982-7922 Ext. 2238
 Fax (513) 874-1600
cmadden@mastersrx.com

